

Remarks

The contents of this paper are identical to the contents of the response filed on April 21, 2010 except for the following, which address issues raised in the Advisory Action and in the Notice of Non-Compliant Amendment:

- the deletion of the recitation of “said combination” in claim 8;
- the deletion of the comma in claim 9 is indicated by double brackets; and
- the replacement in claim 18 of “uthe” with “the.”

Amendments to the Claims

The amendments to the claims comply with matters of form raised in the Final Office Action and present the claims in better form for appeal. The amendments do not add new matter and do not require a new search.

Objection to the Claims

The Final Office Action maintained the objection to claims 1, 3, 4, 8, 9, and 18 “for not leaving a space after the limitation ‘SEQ ID NO:.’” The sequence listing rules are set forth in 37 C.F.R. §§ 1.821 – 1.825 and discussed in M.P.E.P. §§ 2420 – 2435. There is no requirement in either authority for a space after “SEQ ID NO:.” Neither authority contains any example in which a space follows “SEQ ID NO:.” Applicants respectfully request that the objection be withdrawn or that the authority for making the objection be set forth clearly in the next Office Action.

Rejections Under 35 U.S.C. § 112 ¶ 2

The Final Office Action maintained the rejections of claims 10, 12, 13-15, and 18 as set forth in the Office Action mailed March 3, 2009. The amendments to claim 1, discussed below, moot the maintained rejection of claims 13-15. This response also:

- amends claim 10 to recite “at least one of the isolated GBS polypeptide antigens”;
- corrects the spellings of “*N. meningitidis*” and “pertussis” in claim 12; and
- amends claim 18 to delete the recitation “as represented by.”

The Final Office Action newly rejects claims 1, 3, 4, 7-15, and 18-23 under 35 U.S.C. § 112 ¶ 2 as indefinite. Each of items (a) – (k) under this rejection is addressed below.

(a) – (c) Claims 1, 3, 8, 9, and 18 are amended as suggested in the Final Office Action to recite “the GBS 80” and “the GBS 322.”

(f) Claim 19 is amended to clarify that the isolated GBS saccharide antigen is a GBS serotype 1a saccharide antigen.

(g) Claim 3 is amended to delete “the immunogenic fragment of the GBS 80.”

(h) Claim 1 is amended to delete GBS 691. The sequence identifier for GBS 691 in claim 4 is correct.

(i) Claim 7 is amended to clarify that the composition further comprises a third isolated GBS antigen.

(j) Claim 8 is amended to recite “the GBS 691.”

(k) The amendments to claim 1 moot the alleged indefiniteness of claims 3, 4, 7-15, and 18-23.

Please withdraw the rejection.

Rejection Under 35 U.S.C. § 112 ¶ 1 (new matter)

Claim 4 is rejected under 35 U.S.C. § 112 ¶ 1 as allegedly containing new matter. Claim 4 is amended to reinstate the Markush group and to clarify that the antigens in the Markush group are isolated polypeptides. Please withdraw the rejection.

Rejection Under 35 U.S.C. § 103(a)

The Final Office Action maintained the rejection of claims 1, 3, 7, 10-15, and 18-23 under 35 U.S.C. § 103(a) as obvious over WO 02/34771 in view of Wessels (*Inf. Immun.* 61, 4760-66, 1993). Applicants again traverse the rejection.

The determination of whether obviousness is established by combining references must be based on “what the combined teachings of the references would have suggested to those of ordinary skill in the art.” *In re GPAC Inc.*, 57 F.3d 1573, 1581 (Fed. Cir. 1995) (internal quotations omitted). In *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007), the Supreme Court emphasized “an expansive and flexible approach” to the obviousness question. 550 U.S. at 418. The Court also reaffirmed, however, that “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *Id.* The Court stated:

[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements *in the way the claimed new invention does . . .* because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

550 U.S. at 418-19 (emphasis added). *See also* 550 U.S. at 418 (requiring a determination of “whether there was an apparent reason to combine the known elements *in the fashion claimed by the patent at issue*”) (emphasis added).

The Final Office Action states that (1) the claims use the open language “comprising,” so that the claimed compositions can include more antigens than the specific pairs of antigens recited in the claims, particularly the elected combination of GBS 80 and GBS322; and (2) WO 02/34771 discloses GBS 80 and GBS 322. As explained in the response filed November 4, 2009, WO 02/34771 discloses thousands of GBS proteins. The rejection does not set forth any reasoning why it would have been obvious to select any of the particular pairs of antigens recited in independent claim 1.

In fact, the Examiner asserts that no such reasoning is required! See page 7, lines 7-10: “no reasoning as to why WO 02/34771 would have motivated one of ordinary skill in the art to select any of the particular combinations of GBS antigens is warranted since the composition of WO 02/34771 already contains the two recited polypeptides.” This is not the law. As the Supreme Court stated in *KSR*, “there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” 550 U.S. 398, 418 (2007), citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006).

Moreover, it is black letter law that a determination of *prima facie* obviousness cannot be based on a hindsight use of Appellants’ specification to pick and choose isolated elements of a reference and piece them together using Applicants’ specification as a template:

[s]tatements [in a prior art reference] cannot be viewed in the abstract. Rather, they must be considered in the context of the teaching of the entire reference. Further, a rejection cannot be predicated on the mere identification in [the reference] of individual components of claimed limitations. Rather, particular findings must be made as to the reason the skilled artisan, with no

knowledge of the claimed invention, would have selected these components for combination in the manner claimed.

In re Kotzab, 217 F.3d 1365, 1371 (Fed. Cir. 2000). *See also Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1374 n.3 (Fed. Cir. 2008) (cautioning that “[w]e must still be careful not to allow hindsight reconstruction of references to reach the claimed invention without any explanation as to how or why the references would be combined to produce the claimed invention”).

The unsupported assertion that claims 1, 3, 7, 10-15, and 18-23 are obvious over WO 02/34771 in view of Wessels could only have been made with an impermissible hindsight use of Applicants’ specification. Absent the teaching in Applicants’ specification of the combination of GBS80 and GBS322, one of skill in the art would not have been directed to select this combination from the numerous possibilities available from the WO 02/34771 disclosure.

The Federal Circuit has clearly instructed that “where a defendant merely throw metaphorical darts at a board filled with combinatorial prior art possibilities, courts should not succumb to hindsight claims of obviousness.” *In re Kubin*, 561 F.3d 1351, 1359 (Fed. Cir. 2009). This rejection is just such a situation. The fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness. *In re Baird*, 16 F.3d 380, 382 (Fed. Cir. 1994).

There are no facts of record which support an assertion that one of ordinary skill would have been motivated to select from WO 02/34771 the combination of antigens recited in the pending claims. The rejection does not provide the required rational underpinning to support the rejections. *See KSR*, 550 U.S. at 418: “[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”

The Office Action has not made a *prima facie* case that claims 1-4, 10-15, and 18-23 are obvious. Please withdraw the rejection.

Respectfully submitted,

BANNER & WITCOFF, LTD.

/Lisa M. Hemmendinger/

By: _____

Lisa M. Hemmendinger

Registration No. 42,653

Date: May 6, 2010

Customer No. 22907

202-824-3000